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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,692	12/12/2001	James E. Kipp	IDD 5657 CIP3	9772
7590	11/04/2003		EXAMINER	
MARK J. BUONAIUTO, ESQ. BAXTER INTERNATIONAL INC. LAW DEPARTMENT ONE BAXTER PARKWAY, DF2-2E DEERFIELD, IL 60015			OH, SIMON J	
			ART UNIT	PAPER NUMBER
			1615	
			DATE MAILED: 11/04/2003	16

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/021,692	KIPP ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Simon J. Oh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 11 August 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-126 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-126 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

**DETAILED ACTION**

***Papers Received***

Receipt is acknowledged of the applicants' amendment, response, and petition for extension of time, all received on 11 August 2003.

***Double Patenting***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The provisional rejection of Claims 1-66 under 35 U.S.C. 101 as claiming the same invention as that of Claims 1-59, 110-115, and 119 of copending Application No. 09/953,979 is hereby withdrawn

The provisional rejection of Claims 67-97 under the judicially created doctrine of double patenting over Claims 1-120 of co-pending Application No. 09/953,979 is maintained.

Claims 1-66 are provisionally rejected under the judicially created doctrine of double patenting over Claims 1-120 of co-pending Application No. 09/953,979. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 6, 12, 21, 30, 35, 47, 57, 72, 98, under 35 U.S.C. 112, second paragraph, as being indefinite is hereby withdrawn.

The rejection of Claim 127 under 35 U.S.C. 112, second paragraph, as being indefinite is rendered moot with the cancellation of that claim.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-5, 10, 11, 17-20, 25-29, 31-34, and 39 under 35 U.S.C. 102(b) as being anticipated by Stainmesse *et al.* is hereby withdrawn.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-5, 7-20, 22-29, 31-34, 36-46, 48-56, 58, 59, and 66-97 under 35 U.S.C. 103(a) as being unpatentable over Stainmesse *et al.* is maintained.

The rejection of Claims 60-65 and 98-128 under 35 U.S.C. 103(a) as being unpatentable over Stainmesse *et al.* in view of Hanna *et al.* is maintained.

***Response to Arguments***

Applicant's arguments filed 11 August 2003 have been fully considered but they are not persuasive.

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Regarding the current rejection of double patenting, in the instant application, the applicants have failed to recite any positive method steps that clearly disclose how such crystalline particles can be made, in a way as to render the instant claims patentably distinct from the claims in the 09/953,979 application. Hence, the instant claims will remain rejected for double patenting.

The disclosure in the Stainmesse *et al.* patent in which the mixture of the two liquid phases is subjected to moderate stirring is considered by the examiner to read on the applicants' claim limitation of adding energy to a pre-suspension (See Column 2, Lines 43-46). Without any further definition of the type of energy to be added to the pre-suspension in those instant claims that are broad, the step of moderate stirring disclosed in the prior art is interpreted by the examiner to be a step of adding mechanical energy to a pre-suspension. Furthermore, the applicants have taken a narrow interpretation of the prior art. At the most, the prior art passages cited by the applicants disclose embodiments that may be non-preferred, rather than inoperable altogether. As such, the examiner does not see within the disclosure of the prior art a statement that specifically bars the use of an energy-addition step.

The examiner does not consider the indomethacin example cited by the applicants in the prior art to be particularly limiting to the scope of the disclosure of the methods of the prior art. As the methods of the prior art can be applied to various substances, it is the position of the examiner that the state of the particles (crystalline or non-crystalline) produced by the prior art depend upon, or are influenced by the nature of the substance to be made into sub-micron particles. Absent a demonstration made by the applicants showing otherwise, the examiner will not

consider the scope of the methods of the prior art to be limited solely to the production of non-crystalline particles for all substances disclosed therein.

Accordingly, since the examiner does not interpret the disclosure of the Stainmesse *et al.* patent to be strictly limited in scope to the manufacture of non-crystalline particles, the rejection based upon the combination of disclosures from that reference with the Hanna *et al.* patent is deemed proper and is maintained. The claims will remain rejected.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sjo



THURMAN K. PAGE  
SUPervisory Patent Examiner  
TECHNOLOGY CENTER 1600